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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,448	07/07/2003	Lawrence A. Shimp	285-180 PCT CIIP	7536
28249	7590	08/11/2006		EXAMINER
DILWORTH & BARRESE, LLP 333 EARLE OVINGTON BLVD. UNIONDALE, NY 11553			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/614,448	SHIMP, LAWRENCE A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 May 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-88 is/are pending in the application.  
 4a) Of the above claim(s) 2-29,31,36-51,53-63 and 66-88 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,30,32-35,52,64 and 65 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## DETAILED ACTION

1. Applicant's response filed 19 May 2006 to Office Action mailed 17 April 2006 is acknowledged and entered.

2. Examiner very much appreciates that the applicant has labeled each page of the response referred above with Serial Number of the Non-Provisional U.S. Application, the date of the Office Action to which the applicants are responding and attorney's docket number. This practice in and of itself immensely ameliorates the chances of papers lost during transaction/transmission of paper once a filing/response arrives at the United States Patent and Trademark Office (i.e., USPTO). However, after a response/filing arrives at the USPTO, the claims, remarks, amendments etc., are separated for proper coding to scan them in the electronic file wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded and placed in the same application electronic file wrapper, and to further facilitate the prosecution; especially during a telephonic conversation/ interview with applicant/applicants' representative, Examiner suggests that applicants recite in addition to citing the information they already have in the header of the each page for any filing/response/amendment, the following information:

- a. Filing date for said application;
- b. First Applicant's name;
- c. Group Art Unit Number (e.g., 1655);
- d. Examiner's name (e.g., Dr. Kailash C. Srivastava); and
- e. the date that the response is filed

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

3. Applicant to note that at page 7 of the list of Claims accompanying the response filed 19 May, 2006, Claims 52-53 are written twice. Appropriate correction is required.

## Claims Status

4. Claims 1-88 are pending.

## Restriction/Election

5. Applicant's election filed 19 May 2006 with traverse of Group VIII comprising Claims 1, 30, 32-35, "53" and 64-65 in response to Office Action mailed 18 April 2006 is acknowledged and entered. Applicant's traversal is on the grounds that the election requirement in the Office Action cited *supra* is

"improper" and that " Examiner has not met his burden for establishing the need for restriction" (See remarks page 14, Lines 12-14). Citing M.P.E.P. §806.04, Applicant further argues that an where an application includes claims directed to different embodiments or species that could fall within the scope of a generic claim, restriction between the species may be proper, if the species are independent or distinct" (see Remarks, Page 14, Lines 26-29). Applicant also argues that "Groups I-XIV are necessarily related: Claim 1 is the only pending independent Claim and is common to all groups" (see Remarks, Page 16, Lines 28—29) and "examiner provides no discussion of the relationship of the claimed inventions nor any reasoning following from the discussion of the relationship for why the relationship does not prevent restriction..... inadequate" (See remark Page 16, Lines 31-34).

6. Applicant to note that contrary to Applicant's contention, Examiner clarifies on record that Group VIII of the election requirement in Office Action cited *supra* encompasses Claims 1, 30, 32-35, 52 and 64-65; not Claims 1, 30, 32-35, 53 and 64-65.

7. Examiner has fully and carefully considered Applicants' arguments presented in response cited *supra*, however, those arguments are not found persuasive because of the reasons of record on pages 2-5 in Office Action cited *supra* and additional reasons given hereunder.

- i. In regard to applicant's argument that all the claims are dependent on Claim 1 and claim 1 is the only independent claim, therefore, inventions I-XIV are interrelated, Examiner has clearly stated that Clam 1 is a linking Claim that links a number of inventions (see Office Action, Page 4, Item 7) and what are applicant's options for the consideration of all the claims in the application if Claim 1 were to be found allowable;
- ii. As to the distinctiveness of inventions I-XIV, and their inter-relationships, Examiner has given that discussion (See Office Action, Pages 4-5, item 8, lines 2-12; Page 5, Lines 20-22);
- iii. In addition, the search for each of the distinct inventions of Groups I-XIV is not co-extensive particularly with regard to the literature search because each of the inventive groups requires a different search strategy, moreover, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group;
- iv. the burden lies not only in the search of U.S. patents, burden also lies in the search for the scientific and technical literature published in non-patent citations and foreign patents and examination of for e.g., the claim language and specification for compliance with the statutes concerning new matter, written disclosure and distinctness and scope of enablement. Clearly different searches and issues are involved with each group; and
- v. the condition for patentability is different in each case.

For these reasons, the restriction requirement is still deemed proper, is adhered to and is made FINAL.

8. Accordingly, Claims 2-29, 31, 36-51, 53-63 and 66-88 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP §821.03. Examiner suggests that in response to this Office action, the non-elected claims 2-29, 31, 36-51, 53-63 and 66-88 be canceled to expedite prosecution.

9. Claims 1, 30, 32-35, 52 and 64-65 are examined on merits.

### **Priority**

10. Applicant's claim for domestic priority under 35 U.S.C. § 119(e) to Provisional U.S. Application Serial Number 60/259,680 filed 4 January 2001 is acknowledged.

11. Applicant's claim for foreign priority under 35 U.S.C. § 119(a-d) to PCT/US02/00102 filed 4 January 2002 is acknowledged.

### **Information Disclosure Statement**

12. Applicant's Information Disclosure Statements (i.e., IDSs) filed 01 October 2003 has been made of record and considered.

### **Objection To Claims**

13. Claims 30, 32-35, 52 and 64-65 are objected to because of the following minor informalities:

- at Line one of each one of the cited Claims, before the word "wherein" a --, -- should be inserted.
- In Claim 34, at Line two, before the phrase, "gas, a --, -- should be inserted.

Appropriate correction is required.

Examiner has not checked all the Claims to the extent necessary to determine the presence of all possible minor errors/ verbose terms or repugnant words. Applicant's cooperation is required in correcting any errors of which applicant may become aware in the Claims. Applicant is warned to be careful to not add any new matter while revising the Claims for corrections to eliminate any verbose or repugnant or incorrect terms/language.

### **Claim Rejections - 35 USC § 103**

14. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

15 Claims 1, 30, 32-35, 52 and 64-65 are rejected under 35 U.S.C. § 103 (a) as obvious over the combined teachings from Sierra et al. (WO 98/31403) in view of Peterson (U.S. Patent 5, 730,933) and further in view of Higgins (U.S. Patent 5,753, 182).

Claims recite a method to protect a property of a biological material during sterilization of said biological material via packaging said biological material under vacuum or in an inert atmosphere and subsequently sterilizing said package under said atmosphere to reduce or inactivate "adventitious agents". Claims further recite that the reducing atmosphere is comprised of one among hydrogen, hydrogen sulphide or carbon monoxide and inert atmosphere is comprised of nitrogen or argon, wherein the biological material is bone or tissue.

Sierra et al. teach a method, wherein a collagen based surgical tissue formulation as a tissue adhesive composition placed in an appropriate container (e.g., syringe or a frame) is first dried via lyophilization, freeze-drying or dried under vacuum (Page 8, Lines 2-5; Page 12, Lines 26-29 and Page 26, Lines 20-21) and subsequently radiation- sterilized with an electron beam (i.e., e-beam) or gamma radiation (Page 27, Lines 1-3; in a temperature range of 0° C to ambient (i.e., room temperature). During irradiation, the collagen-based material is kept cool (i.e., at temperature between -40°C to 10°C), while being exposed to e-beam irradiation at a dosage in range of 10-40 KGy (Page 14, Lines 3-13), or gamma radiation (Page 27, Lines 19-20). Note that Sierra et al teach radiation sterilization of a biological material and therefore, intrinsically teach radiation sterilization of a bone, because bone is also a biological material. Sierra et al. do not teach radiation sterilization discussed *supra* is conducted in presence of an inert gas, e.g., argon (Ar), helium (He) or nitrogen (N<sub>2</sub>) mixed with hydrogen (H<sub>2</sub>) or in presence of hydrogen in an inert atmosphere (e.g.. vacuum). Peterson teaches a method for radiation sterilization of a bioactive material with gamma or electron beam (Column 2, Lines 42-45), wherein prior to irradiation, said bioactive material is subjected to vacuum or an inert gaseous atmosphere comprised of argon, helium, neon, or nitrogen (Column 5, Lines 29-31). Said material is lyophilized, vacuum dehydrated or freeze-dried prior to irradiation (Column 5, Lines 53-57) and is held in a sealed or unsealed container for irradiation (Column 6, Lines 19-25). Higgins beneficially teaches that the biological material is packaged in a material that is permissive to hydrogen, but not to oxygen in vacuum or an inert gaseous atmosphere

is irradiation sterilized through gamma irradiation, in presence of hydrogen gas (Column 2, Lines 38-66 and Column 6, Lines 20-29, 48-50 and 54-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings from Sierra et al. according to the teachings of Peterson and Higgins to obtain a method to sterilize a biologically active material through gamma, or electron beam irradiation in an atmosphere of hydrogen, wherein said biological material was packaged in an unsealed or sealed package, dried through lyophilization, critical point drying or other methods of drying and subsequently said packaged biological material kept in an inert atmosphere comprising either vacuum or of inert gases or in an atmosphere of inert gases mixed with hydrogen, prior to said radiation mediated sterilization; because, Sierra et al. teach a method, wherein a biologically active material placed in an appropriate container is dried via lyophilization, freeze-drying or dried under vacuum and subsequently radiation- sterilized with an electron beam (i.e., e-beam) or gamma radiation at a temperature in range of 0°C and ambient and Petersen substantiates Sierra et al's teachings because Petersen teaches an inert gaseous atmosphere for sterilizing a biological material and Higgins teaches sterilization of a biological material in a reduced gaseous atmosphere (i.e., hydrogen). The prior art references discussed *supra* do not teach exactly same dimensions for each of the parameter for irradiation -mediated sterilization of a biologically active material. However, the adjustment of particular conventional working conditions (e.g., irradiation dosage, temperature during irradiation, means to dry the sample and type of inert gas atmosphere) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan. In view of the fact that the applicants' invention also recites a method to sterilize a biologically active material.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify the teachings from Sierra et al., according to combined teachings from Petersen et al. and Higgins, because as discussed in the previous paragraph, the cited prior art references teach a method to sterilize a biological material according to same steps and applying the same conditions and components as is claimed instantly.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Claim Rejections - 35 U.S.C. § 112***

16. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

17. Claims 1, 30, 32-35, 52 and 64-65 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- The recitation, "desired" in Claim 1 is similar to the word "preferably" and is indefinite because it is not clear how one can determine with clarity and accuracy when the "desire" is to be exercised and what are the metes and bounds of the term. Applicant is required to define the metes and bounds for the term, "desire".
- The phrase "adventitious agent(s)" renders Claim 1 vague and therefore indefinite because the metes and bounds for said phrase are not defined. Applicant is required to define the metes and bounds for the phrase, "adventitious agent (s)".
- Claim 1 is also rendered vague and indefinite by the use of parentheses. The use of parentheses encompassing terminology in the claims is indefinite because it is unclear if what is stated within the parentheses is a further limitation or simply alternative meaning.
- Claim 8 as recited currently seems to be incomplete because it is not clear what is mixed with what and what is the inert mixture, e.g., See Line 4. Appropriate correction is required.
- Claim 65 as presented currently does not advance in any way the limitations for Claim 52.

All other claims depend directly or indirectly from the rejected claims (e.g., Claims 1) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

## Conclusion

18. For reasons aforementioned, no Claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 9:00 A.M. to 5:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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August 7, 2006

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